

In the Claims:

Please amend the Claims as shown in Appendix A.

The format of the amendments in Appendix A complies with the January 31, 2003 Pre-OG Notice found at:

<http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/revamdtprac.htm>.

In the Specification:

Please amend the Paragraph on Page 11, lines 7-24 as shown in Appendix B. The format of the amendment in Appendix B also complies with the January 31, 2003 Pre-OG Notice.

Remarks

Claims 1-5, 7-9, 11, 13-15, 31, 38, 54, 61, 129-132, 134-136, 138, 140-146, 148-150, 152, 154-160, 162-164, 166, and 168-185 have been amended.

Claims 6, 10, 12, 133, 137, 139, 147, 151, 153, 161, 165, and 167 have been canceled.

Claims 1-5, 7-9, 11, 13-15, 31, 38, 54, 61, 129-132, 134-136, 138, 140-146, 148-150, 152, 154-160, 162-164, 166, and 168-185 remain in the application.

Except as noted in the paragraph immediately below, all Claim amendments are purely formal in nature, and are not intended to alter the scope of the Claims in any manner.

In addition to the purely formal Claim amendments, Claims 1 and 38 were amended, and Claims 6, 10, 12, 133, 137, 139, 147, 151, 153, 161, 165, and 167 were canceled, in order to delete references in the Claims to the herbicides sulfometuron methyl, chlorimuron ethyl, and rimsulfuron. In drafting the January 2, 2003 amendment, the undersigned overlooked the fact that, in the course of limiting the scope of the pending Claims to derivatives of the plant with ATCC accession number

PTA-904, it was no longer appropriate to refer to resistance to particular herbicides against which field tests had shown that PTA-904 was not particularly resistant. References to the three herbicides in question have accordingly been deleted from the Claims.

The specification has been amended at page 11, line 12 to refer to specific ATCC deposit numbers for certain lines of rice. See headings 7 and 14 below for further discussion regarding the amendments to the specification.

If any extension of time is required, please consider this paper a petition for the total extension of time required.

It is believed that no fee is due in connection with this paper. In the event that the Office determines that a fee is due, kindly refer to the general Deposit Account Authorization previously filed with the application.

Reexamination and reconsideration of the application, as amended, are respectfully requested.

Topic numbers in the headings below (e.g., "5-6" in the heading immediately below) correspond to those appearing in the March 10, 2003 Office Action. Topic numbers omitted below (e.g., 1-4) are believed not to require any response.

5-6. The Two Information Disclosure Citations

Concerning the September 17, 2001 Information Disclosure Citation, the Office stated that while patent application 09/934,973 had been considered, its citation had been crossed out because an application is not a proper reference to print on the face of a patent. Although the Office cited no authority in support of this position, the Office's statement shows that the prosecution history will reflect that Applicant has fulfilled any duty of candor that may exist respecting the '973 application, and that the Office has considered that application in connection with the examination of the present application.

Concerning the July 30, 2001 Information Disclosure Citation, to help avoid possible future misunderstandings when others might review the file history of this application, the Office is respectfully requested to re-mail an initialed copy of the July 30, 2001 Information Disclosure Citation, marked to show that all references cited on page 4 were considered, not just the first and last entries shown on that page.

7. The Objection to the Specification

The Office Action objected to the specification at page 11, line 12 for not giving actual ATCC accession numbers.

The specification has been amended at page 11, line 12 to refer to specific ATCC deposit numbers for certain lines of rice. The same amendment has in fact previously been submitted, as part of the annexes to the International Preliminary Examination Report, the entry of which was specifically requested on April 23, 2001 when the United States national stage was entered. The March 10, 2003 Office Action suggests, however, that this earlier amendment to the specification may have been overlooked. In the interest of expediting prosecution, an amendment to page 11 that is identical in substance to the earlier amendment from the international stage is being presented again. The amendments to page 11 of the specification are highlighted in Appendix B (by strikeout and underlining) as compared to the PCT international application originally filed on November 5, 1999.

The amendments to page 11 of the specification substitute actual American Type Culture Collection accession numbers for several deposited lines of rice seeds, e.g. --PTA-904--, for "placeholders" that were used in the application as filed e.g., "aaaaa." Seed samples from each of the rice lines in question were deposited with the American Type Culture Collection on November 2, 1999, prior to the November 5, 1999 international filing date. However, the accession numbers had not been received as of the international filing date. Attached as Appendix C are two forms from the American Type Culture Collection, both dated November 22, 1999, and both acknowledging

deposit of the seeds under the Budapest Treaty on November 2, 1999. Thus there is no question of new matter.

It is respectfully submitted that this ground of objection should be withdrawn.

8. The Claim Objections

The Office objected to various dependent Claims on the ground that phrases such as "A rice plant" or "A process" should instead read --The rice plant-- or --The process-- to denote that the dependent claims further limited the plant or process recited in the parent claim. Although no authority was cited in support of this position, in the interest of expediting prosecution the suggested Claim amendments have been made.

These amendments are purely formal in nature, and are not intended to alter the scope of any of the Claims in any manner.

It is respectfully submitted that this ground of objection should be withdrawn.

9-10. The § 112, Second Paragraph Rejections

All Claims were rejected under 35 U.S.C. § 112, second paragraph as being indefinite on either of two grounds.

Derivatives

Claim 1 was said to be indefinite in its use of the phrase "is a derivative of the plant" because there are many ways to derive a rice plant.

It is certainly true that there are many ways to derive a rice plant. But that observation does not mean that the Claim is indefinite.

It should be kept in mind that a claim is definite if its scope is clear. If the metes and bounds of a claim are clearly ascertainable, then the claim, no matter how broad, may not properly be rejected under § 112, second paragraph. As stated by the Court of Customs and Patent Appeals, one of the two predecessor courts to the Court of

Appeals for the Federal Circuit, if each of the limitations of a claim is definite, then the claim is definite and may not be rejected under section 112, second paragraph. *In re Goffe*, 526 F.2d 1393, 1397-98; 188 USPQ 131, 135 (CCPA 1975).

It is axiomatic that a patent applicant is entitled to be his own lexicographer. The present specification defines what is meant by a "derivative" of a herbicide-resistant plant, and confirms that the expression is intended to have a broad, but definite, interpretation. See page 31, line 31 to page 32, line 6:

Unless otherwise clearly indicated by context, the "progeny" of a plant includes a plant of any subsequent generation whose ancestry can be traced to that plant.

Unless otherwise clearly indicated by context, a "derivative" of a herbicide-resistant plant includes both the progeny of that herbicide-resistant plant, as the term "progeny" is defined above; and also any mutant, recombinant, or genetically-engineered derivative of that plant, whether of the same species or of a different species; where, in either case, the herbicide-resistance characteristics of the original herbicide-resistant plant have been transferred to the derivative plant. Thus a "derivative" of a rice plant with a resistant AHAS enzyme would include, by way of example and not limitation, any of the following plants that express the same resistant AHAS enzyme: F_1 progeny rice plants, F_2 progeny rice plants, and F_{30} progeny rice plants.

A Claim is definite if its scope is clear, regardless of how broad the Claim might be. The meaning of "derivative" as used in these Claims is clear. It is respectfully submitted that this ground of rejection should be withdrawn.

Strictly in the alternative, this ground of rejection should be withdrawn at least for Claims 31, 54, 129-132, 134-136, 138, 140-142, 157-160, 162-164, 166, and 168-175, and 183-185, each of which contains, in addition to the "derivative" limitation, a further limitation directed to the rice plant with ATCC accession number PTA-904 or progeny of the plant with ATCC accession number PTA-904.

“ATCC accession number PTA-904”

Claims 1, 31, 54, and 171 were said to be indefinite in their use of the phrase “ATCC accession number PTA-904,” because the specification did not teach “ATCC accession number PTA-904.”

Without conceding the validity of this ground of rejection, it is respectfully submitted that the present amendment to page 11 of the specification, which, among other things, refers to ATCC accession number PTA-904, overcomes this ground of rejection.

§ 112, Second Paragraph Summary

It is respectfully submitted that all § 112, second paragraph rejections should be withdrawn.

Strictly in the alternative, this ground of rejection should be withdrawn at least for Claims 31, 54, 129-132, 134-136, 138, 140-142, 157-160, 162-164, 166, and 168-175, and 183-185, each of which contains, in addition to the “derivative” limitation, a further limitation directed to the rice plant with ATCC accession number PTA-904 or progeny of the plant with ATCC accession number PTA-904.

11. The § 112, First Paragraph Rejections

The March 10, 2003 Office Action entered three grounds of rejection under 35 U.S.C. § 112, first paragraph: a “written description” rejection, an “enablement” rejection, and a rejection pertaining to the deposit of seeds under the Budapest Treaty. Each of the three grounds of rejection is discussed below.

12. The Written Description Rejection

All Claims were rejected as containing subject matter that lacked an adequate written description in the specification.

The Office Action at page 6 cited M.P.E.P. § 2163, subpart (I)(A) for the proposition that a “claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function.” The quoted section does not purport to represent an absolute rule; rather, it is intended to alert one to a possibility, a possibility that may or may not exist, depending on the facts of a particular case: “The claimed invention as a whole *may* not be adequately described . . .” (emphasis added)

The specification in fact describes a correlation between the structure and the function of the claimed rice plants: a rice plant that is derived from PTA-904, and that retains the herbicide resistance characteristics of PTA-904, will be resistant to certain herbicides.

But more importantly, it should be kept in mind that the structure-function question is only subsidiary. As previously discussed, the purpose of this subsidiary question is merely to alert one to a particular possibility, a possibility that should be evaluated in light of the individual circumstances. The principal, underlying question is the following: “To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention.” M.P.E.P. § 2163, subpart (I), second paragraph, citation omitted. The present specification clearly demonstrates that the Applicant had possession of the claimed invention.

As stated in M.P.E.P. § 2163, subpart (II)(A)(3)(a), first paragraph: “Possession may be shown in many ways. For example, possession may be shown by describing an actual reduction to practice of the claimed invention.”

The specification describes, in detail, the actual reduction to practice of herbicide resistant rice in accordance with the present invention. See, e.g., page 10, line

14 through page 11, line 24. The "parent" line PWC16 was deposited with ATCC and given accession number PTA-904. See, e.g., page 11, lines 7-24 (as amended).

The preceding discussion should suffice to demonstrate that the present application satisfies the written description requirement. But for the sake of completeness, and in the event that prosecution of this application might thereby be accelerated, below are brief answers to four questions raised on pages 5 and 6 of the March 10, 2003 Office Action.

(i) The Office Action asserted that the Applicant had not described the specific mutation that had occurred. The mutation is that found in the AHAS enzyme of the rice plant with ATCC accession number PTA-904, where the mutant enzyme imparts to the rice plant resistance "to inhibition by one or more of the following herbicides, at levels of herbicide that would normally inhibit the growth of a rice plant: imazethapyr, imazapic, imazapyr, nicosulfuron, imazaquin, imazamox, metsulfuron methyl, thifensulfuron methyl, tribenuron methyl, pyrithiobac sodium, or a derivative of any of these herbicides." See also the discussion of topic (iv) below.

(ii) The Office Action asserted that the Applicant had not described how to distinguish the claimed herbicide resistant rice plants from other herbicide resistant rice plants.

Determining the herbicide resistance characteristics of a particular line of a crop plant can only be described as routine. Some of the more significant herbicide resistance characteristics of PTA-904 are illustrated, for example, in the test results shown on pages 16-24 of the specification. Comparing the AHAS-acting herbicide resistance characteristics of any particular rice line to those of PTA-904 may readily be conducted through routine experimentation -- e.g., spray the plants, and observe their reaction. Note that as a practical matter, it should usually only be necessary to test resistance to AHAS-acting herbicides that are contemporaneously being sold commercially for use on crops.

Before the inventions described in the present application were reduced to practice, no source of AHAS herbicide resistance in rice was known -- whether naturally occurring or artificially induced -- having the superior AHAS-acting herbicide resistance characteristics of PTA-904 (as discussed further below under heading no. 20, the provisional obviousness-type double patenting rejection, and in the enclosed new Affidavit of Dr. Croughan). Thus a rice plant that has the herbicide resistance characteristics of PTA-904 should be presumed to be derived from PTA-904, in the absence of satisfactory evidence to the contrary. If no source is known in the art for rice having such herbicide resistance characteristics, other than the inventor's own teachings, and if a person making and selling such rice cannot demonstrate its derivation from a separate source, then it is only fair to presume that the rice was derived from PTA-904. Put differently, if element (c) of Claim 1 is satisfied, then it is only fair to presume that element (b) is also satisfied, in the absence of convincing evidence suggesting otherwise.

(Note that the possible presence of additional herbicide resistance traits, derived from sources other than PTA-904, is not precluded by this limitation -- provided that the plant in question expresses resistance to the AHAS-acting herbicides to which PTA-904 is resistant.)

Furthermore, it should be kept in mind that it is a nearly universal practice that the developer or breeder of a new rice cultivar will disclose publicly the ancestry of the variety (except for a small number of proprietary hybrids). See, for example, the present specification at page 10, lines 15-17, where the present inventor disclosed the "parentage" of PTA-904. While it may not have been strictly necessary to do so for purposes of satisfying the patent statute, this information was nevertheless supplied as second nature by the inventor, as it is customary in the rice breeding art to do so. Similarly, as a practical matter one is very likely to know the pedigree of any publicly released rice cultivar.

For either of these reasons one should readily be able to determine the ancestry of a rice variety accused of infringing these claims should it be necessary to do so: (1) a

presumption that rice having the same herbicide resistance characteristics shares the same derivation, in the absence of evidence suggesting otherwise; and (2) the nearly universal practice in the art of publicly disclosing the ancestry of new rice cultivars.

(iii) The Office Action asserted that the written description of the specification lacked a reference to ATCC accession number PTA-904. Without conceding the validity of this point, it is respectfully submitted that the current amendment to page 11 of the specification overcomes this ground of rejection.

(iv) The Office Action asserted that Applicant does not know the mechanism of herbicide resistance in the PTA-904 line. On an initial point, it should be kept in mind that the patent law imposes no requirement that an inventor must understand why an invention works. It suffices that the invention does in fact work. Note further that none of the Claims pending in the present application contain limitations directed to a generic description of a category of herbicide resistance. Rather, independent Claim 1 requires specifically that “(b) said plant is a derivative of the plant with ATCC accession number PTA-904; and (c) said plant has the herbicide resistance characteristics of the plant with ATCC accession number PTA-904.” This limitation does not go beyond the written description.

Furthermore, to the extent that the patent law might be interpreted as requiring that the inventor know the underlying mechanism why an invention works (and it is repeated that the law imposes no such requirement), the Office’s attention is respectfully directed to the December 18, 2002 Affidavit of inventor Timothy P. Croughan, filed on January 2, 2003. The data presented in that Affidavit clearly confirm that the herbicide resistance of line PTA-904 is due to a mutant AHAS enzyme, an enzyme that expresses herbicide resistance at the enzyme level. The data presented in the affidavit amply confirm the hypothesis set forth in the specification at page 7, lines 14-34 for rice line PTA-904 -- namely, that herbicide resistance was due to a mutant, herbicide-resistant AHAS enzyme.

Written description summary

It is respectfully submitted that the written description rejection should be withdrawn.

Strictly in the alternative, this ground of rejection should be withdrawn at least for Claims 31, 54, 129-132, 134-136, 138, 140-142, 157-160, 162-164, 166, and 168-175, and 183-185, each of which contains, in addition to the "derivative" limitation, a further limitation directed to the rice plant with ATCC accession number PTA-904 or progeny of the plant with ATCC accession number PTA-904.

13. The Enablement Rejection

All Claims were rejected as containing subject matter that was not enabled by the specification. The Office presented several sub-arguments pertaining to enablement, some of which had counterparts in the Office's arguments concerning written description, and some of which did not.

The following enablement arguments are understood to be essentially the same as the counterpart arguments concerning written description. For the same reasons as given above in the discussion of written description -- reasons that will not be repeated in the interest of brevity -- it is respectfully submitted that the specification fully enables one of ordinary skill in the art to practice the claimed inventions without undue experimentation. These parallel written description / enablement points, those for which the above replies to the written description rejection are also offered in response to the enablement rejection, are the following: (a) the specific mutation responsible for the observed herbicide-resistant phenotype, (b) how to distinguish the claimed plants from other herbicide-resistant rice plants, and (c) whether the specification describes the ATCC deposit with accession number PTA-904.

The remaining points raised in the Office Action concerning enablement are discussed below.

Derivatives of PTA-904

One ground of rejection appears to have been based on an erroneous interpretation of the Claim language. The Office Action asserted at page 9 that "claim 1 can be read to encompass a rice plant that is a 'derivative' of ATCC accession number PTA-904, but the 'herbicide resistance characteristics of the plant with ATCC accession number PTA-904' can be introduced from another rice plant."

As discussed above in connection with the § 112, second paragraph rejections, the specification provides a detailed definition of what it means for one plant to be a "derivative" of another. That discussion will not be repeated here in the interest of brevity, but it is respectfully submitted that the response to the § 112, second paragraph rejection pertaining to "derivatives" also answers this ground of enablement rejection. In brief, Claim 1 requires that the rice plant must, among other things, have herbicide resistance characteristics that may be traced back to the deposited line PTA-904.

Strictly in the alternative, this ground of rejection should be withdrawn at least for Claims 31, 54, 129-132, 134-136, 138, 140-142, 157-160, 162-164, 166, and 168-175, and 183-185, each of which contains, in addition to the "derivative" limitation, a further limitation directed to the rice plant with ATCC accession number PTA-904 or progeny of the plant with ATCC accession number PTA-904.

Herbicide Resistance Characteristics

On pages 8-9, the Office Action asserted that undue experimentation would be required to determine the herbicide resistance characteristics of PTA-904.

With all respect, determining the herbicide resistance characteristics of a particular line of a crop plant can only be described as routine. Some of the more significant herbicide resistance characteristics of PTA-904 are illustrated, for example, in the test results shown on pages 16-24 of the specification. Testing the resistance of PTA-904 or other rice plants to other AHAS-acting herbicides can only be described as

routine. Note further that, as a practical matter, it should only be necessary to test resistance to AHAS-acting herbicides that are contemporaneously sold commercially for use on crops.

A rice plant that is resistant to those AHAS-acting herbicides to which PTA-904 is resistant satisfies the "herbicide resistance characteristics" limitation of Claim 1. Determining whether particular plants have such herbicide resistance characteristics may readily be determined through routine experimentation -- e.g., spray the plants, and observe their reaction.

(Note that the possible presence of additional herbicide resistance traits, derived from sources other than PTA-904, is not precluded by this limitation -- provided that the plant in question expresses resistance to the AHAS-acting herbicides to which PTA-904 is resistant.)

Sulfometuron methyl, chlorimuron ethyl, rimsulfuron, and nicosulfuron.

As previously discussed, claim limitations pertaining to resistance to sulfometuron methyl, chlorimuron ethyl, and rimsulfuron had been carried forward as a drafting oversight by the undersigned when Claim 1 was narrowed on January 2, 2003 to refer to derivatives of ATCC accession number PTA-904. All claim limitations referring to those three herbicides have now been canceled by the present amendment, overcoming this ground of rejection.

The Office Action also questioned resistance to nicosulfuron. As shown in the specification in Table 2, pp. 16-17, and Table 4, pp. 23-24, PTA-904 does express resistance to certain concentrations of nicosulfuron. Thus limitations pertaining to nicosulfuron resistance are enabled.

Enablement Summary

It is respectfully submitted that all grounds of rejection pertaining to enablement have been overcome or should otherwise be withdrawn.

Strictly in the alternative, this ground of rejection should be withdrawn at least for Claims 31, 54, 129-132, 134-136, 138, 140-142, 157-160, 162-164, 166, and 168-175, and 183-185, each of which contains, in addition to the "derivative" limitation, a further limitation directed to the rice plant with ATCC accession number PTA-904 or progeny of the plant with ATCC accession number PTA-904.

14. The Budapest Treaty Seed Deposit

The Claims were rejected based on objections to the deposit of seeds with the American Type Culture Collection.

Without conceding the validity of the Office's objections, the undersigned confirms, over his signature and registration number appearing below, that the American Type Culture Collection seed deposit accession number PTA-904 that is described in the present specification on page 11 was made under the Budapest Treaty, and that all restrictions on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent on the present application.

In addition, attached as Appendix C are two forms from the American Type Culture Collection, both dated November 22, 1999, and both acknowledging deposit of the various seeds under the Budapest Treaty on November 2, 1999, including in particular the deposit of PTA-904.

It is respectfully submitted that this ground of rejection has been overcome or is otherwise now moot.

15-17. The Prior Art Rejection

All Claims were rejected under 35 U.S.C. § 102(b) or § 103(a) as being anticipated by, or obvious over Terakawa.

It appears that the Office may have made a clerical oversight in drafting this portion of the Office Action, as it appears perhaps to have been based on a prior art rejection that was recently entered against Claims having different limitations in the

“continuation” application, S.N. 09/934,973. It does not appear to be based on the limitations of the Claims that are pending in the present case.

Claim 1, the sole independent Claim, includes the limitation that “the growth of said plant is resistant to inhibition by one or more of the following herbicides, at levels of herbicide that would normally inhibit the growth of a rice plant: imazethapyr, imazapic, imazapyr, nicosulfuron, imazaquin, imazamox, metsulfuron methyl, thifensulfuron methyl, tribenuron methyl, pyrithiobac sodium, or a derivative of any of these herbicides.”

Nothing in Terakawa teaches or suggests a rice plant having resistance to any of these herbicides. Instead, Terakawa discloses a rice mutant that was said to be resistant to the herbicide bensulfuron methyl. No resistance to any other herbicides is disclosed or suggested. Bensulfuron methyl is not particularly toxic to rice plants. Terakawa acknowledges as much in the first paragraph on page 268: “However, BSM [bensulfuron methyl] inhibits the root elongation of rice seedling in paddy field occasionally. Although BSM toxicity to rice is not severe, it affects to the initial growth of the rice plants.” In short, Terakawa mentions one side effect of bensulfuron methyl on rice that is seen only “occasionally,” and unequivocally states that “toxicity to rice is not severe.”

In fact, bensulfuron methyl is routinely used as a herbicide on non-resistant rice crops. Had Terakawa discovered resistance to a herbicide that was more toxic to rice than bensulfuron methyl, it is only reasonable to expect that Terakawa would have mentioned that fact. In the absence of such a disclosure by Terakawa, there is no reason to conclude that the rice plant disclosed by Terakawa was resistant to any such herbicides.

Terakawa neither anticipates nor makes obvious the claimed inventions. It is respectfully submitted that the § 102(b) and § 103(a) rejections should be withdrawn.

18. The Obviousness-Type Double Patenting Rejections

Two grounds of obviousness-type double patenting rejection were entered.

19. The Double Patenting Rejection over Croughan, U.S. Patent 5,773,704

All Claims were rejected for obviousness-type double patenting over Claims 1-18 of Croughan, U.S. Patent 5,773,704.

It is respectfully submitted that there are at least three different reasons why this ground of rejection should be withdrawn: (a) The March 10, 2003 Office Action applied an incorrect legal standard to the double patenting question. (b) Even if the standard applied in the Office Action were legally correct (which it is not), that standard would nevertheless have been applied incorrectly to the facts of this case. (c) Under the correct legal standard, applied correctly to the facts of this case, there is no obviousness-type double patenting.

(a) The standard applied in the March 10, 2003 Office Action concerning double patenting is legally incorrect. Without citation of any supporting authority, the standard applied by the Office Action appears to be whether a person of ordinary skill in the art would be able to distinguish a derivative plant covered by the Claims of the '704 patent from a derivative plant covered by the claims of the present application.

This is not the proper legal standard for obviousness-type double patenting. The correct standard is instead the following: "does any claim in the application define an invention that is merely an obvious variation of an invention claimed in the patent?" M.P.E.P. § 804, subpart (II)(B)(1), first paragraph. Under the correct legal standard, the proper comparison is between two claims -- not a comparison between two embodiments.

Brief reflection will readily demonstrate that it would be inappropriate for the governing standard to be whether an embodiment covered by an issued patent could be distinguished from an embodiment covered by a claim in a pending application. As the discussion in M.P.E.P. § 804 demonstrates (e.g., subpart (II)(B)(1)(b)), obviousness-type double patenting questions often arise in the context of a broader genus claim versus a narrower species claim presented in different patent(s) or application(s). If the proper standard were merely whether embodiments could be distinguished, then

obviousness-type double patenting would always exist between a genus claim and a species claim presented in different patent(s) or application(s), because an embodiment covered by a specific claim would always be covered by the generic claim, so that a large part of the discussion in the M.P.E.P. concerning double patenting would be moot. Comparison of embodiments is not the proper legal standard. Instead, one compares Claims.

(b) Even if the standard applied in the Office Action were legally correct (which it is not), the Office nevertheless would have incorrectly applied that standard to the facts of this case. Although it is not logically necessary for the Applicant to demonstrate this point in order to overcome the double patenting rejection, it will nevertheless be discussed briefly, in case doing so might help accelerate the prosecution of this application. The Office Action stated at page 14: "The issued claims do not limit the number of generations away from said deposited plant. The herbicide-resistant rice plant of the instant claims is obvious over the herbicide-resistant plant of the issued patent, because one of ordinary skill in the art would not be able to distinguish the 'derivative' plant of the patented herbicide-resistant rice plant from the 'derivative' plant of ATCC accession number PTA-904 of the instant claims."

As discussed above in connection with the § 112, second paragraph rejection, "derivative" plants must retain the specified herbicide resistance characteristics. See, e.g., the present specification at page 25, lines 1-5, demonstrating that distinguishing lines with different herbicide resistance characteristics is in fact relatively straightforward: "Further examination of these plants led to the conclusion that the following herbicide resistant lines appeared to be identical to prior herbicide resistant line ATCC 97523, presumably because a few seeds of ATCC 97523 from prior trials had remained dormant in the soil between growing seasons: PWC18, PWC20, PWC24, CMC25, CMC26, CMC28, CMC30, WDC32, WDC34, WDC35, and WDC36." (These lines were, accordingly, not among those deposited with ATCC.)

In addition to examining patterns of resistance to various herbicides, it should also be kept in mind that, as previously discussed, it is a nearly universal practice in the art that the developer or breeder of a new rice cultivar will disclose publicly the ancestry of the variety (except for a small number of proprietary hybrids). As a practical matter one is very likely to know the pedigree of any publicly released rice cultivar.

For either of these reasons, it will be possible for one of ordinary skill in the art to distinguish derivatives of ATCC 97523 covered by the '704 patent from rice plants covered by the present Claims.

(c) Under the correct legal standard, applied correctly to the facts of this case, there is no obviousness-type double patenting. The correct legal standard is the following: "does any claim in the application define an invention that is merely an obvious variation of an invention claimed in the patent?" M.P.E.P. § 804, subpart (II)(B)(1), first paragraph.

It is important to keep in mind that when "considering whether the invention defined in the claim of an application is an obvious variation of the invention defined in the claim of a patent, the disclosure of the patent may not be used as prior art." M.P.E.P. § 804, subpart (II)(B)(1), sixth paragraph.

"Any obviousness-type double patenting rejection should make clear: (A) The differences between the inventions defined by the conflicting claims -- a claim in the patent compared to a claim in the application; and (B) The reasons why a person of ordinary skill in the art would conclude that the invention defined in the claim in issue is an obvious variation of the invention defined in a claim in the patent." M.P.E.P. § 804, subpart (II)(B)(1), fifth paragraph.

The Office Action did not even attempt to apply this standard to the double-patenting question. To support this ground of rejection, at a minimum the Office should identify at least one specific Claim from the '704 patent and at least one specific Claim from the present application, and then explain why a person of ordinary skill in

the art would conclude that the latter would have been obvious in light of the former. It is respectfully submitted, however, that this is not the case.

For example, Claim 1 of the '704 patent is as follows:

1. A rice plant wherein:

- (a) the growth of said plant is resistant to inhibition by one or more of the following herbicides, at levels of herbicide that would normally inhibit the growth of a rice plant: imazethapyr, imazaquin, primisulfuron, nicosulfuron, sulfometuron, imazapyr, imazameth, imazamox, or a derivative of any of these herbicides;
- (b) said plant is a derivative of the plants with ATCC accession numbers 75295 and 97523; and
- (c) said plant has the herbicide resistance characteristics of the plants with ATCC accession numbers 75295 and 97523.

By contrast, Claim 1 of the present application reads as follows:

1. (currently amended) A rice plant wherein:

- (a) the growth of said plant is resistant to inhibition by one or more of the following herbicides, at levels of herbicide that would normally inhibit the growth of a rice plant: imazethapyr, imazapic, imazapyr, nicosulfuron, imazaquin, imazamox, metsulfuron methyl, thifensulfuron methyl, tribenuron methyl, pyrithiobac sodium, or a derivative of any of these herbicides; and
- (b) said plant is a derivative of the plant with ATCC accession number PTA-904; and
- (c) said plant has the herbicide resistance characteristics of the plant with ATCC accession number PTA-904.

Note first that as discussed in Paragraph 6 of the December 18, 2002 affidavit of inventor Timothy P. Croughan, filed on January 2, 2003, the ATCC 75295 line

mentioned in Claim 1 of the '704 patent does not have a resistant AHAS enzyme; while, by contrast, PTA-904 does have a resistant AHAS enzyme. Thus the "ATCC 75295" component of the '704 patent does nothing to suggest the present invention, which instead relies on a resistant AHAS enzyme for its herbicide resistance.

Furthermore, nothing in Claim 1 of the '704 patent teaches or suggests any herbicide resistant rice plant having a resistant AHAS enzyme, other than the specific source of resistance from ATCC 97523. There is no suggestion for how to make such a plant, and there would have been no reasonable expectation that such a plant could be successfully produced. There would certainly have been no reasonable expectation that resistant rice AHAS enzymes could be produced having herbicide resistance characteristics different from those of the ATCC 97523 rice.

In particular, there is nothing in Claim 1 of the '704 patent that suggests the markedly superior herbicide resistance characteristics that have been achieved by PTA-904. Please see the enclosed new Affidavit of inventor Timothy P. Croughan, which demonstrates that PTA-904 has herbicide resistance characteristics that are substantially different from those of ATCC 97523, the resistant line that is disclosed in Claim 1 of the '704 patent and that includes a herbicide-resistant AHAS enzyme.

It is respectfully submitted that the obviousness-type double patenting rejection should be withdrawn.

20. The Provisional Obviousness-Type Double Patenting Rejection over Co-Pending Application S.N. 09/934,973

All Claims were provisionally rejected under the doctrine of obviousness-type double patenting over certain Claims of co-pending application S.N. 09/934,973.

It is respectfully submitted that this provisional ground of rejection should be withdrawn for the same three basic reasons: (a) The March 10, 2003 Office Action did not apply the correct legal standard to the double patenting question. (b) The Office Action's conclusion was based on incorrect factual assumptions. (c) Under the correct

legal standard, applied correctly to the facts of this case, there is no obviousness-type double patenting.

(a) The correct legal standard is the following: "does any claim in the application define an invention that is merely an obvious variation of an invention claimed in the patent?" M.P.E.P. § 804, subpart (II)(B)(1), first paragraph.

With all respect, it is difficult to understand what standard was applied in part 20 of the March 10, 2003 Office Action. What the Office Action said (on page 14) was the following:

Copending Application No. 09/934,973 claims a herbicide-resistant rice plant that expresses a functional AHAS enzyme that is resistant to inhibition by at least one herbicide that normally inhibits AHAS. The instant claims are *prima facie* obvious in view of copending Application No. 09/934,973 because the instant claims are directed to "derivative" rice plants and "progeny" rice plants, rice plants of which the nature of the herbicide-resistance is not taught.

While it is not clear what legal standard this paragraph purports to apply, it does not appear to be that set forth in M.P.E.P. § 804, subpart (II)(B)(1), first paragraph.

(b) The Office Action appears to base its conclusions on incorrect factual assumptions. While this part of the Office Action is not entirely understood, it seems to be based on an assumption that the nature of the herbicide resistance of derivatives and progeny is not taught by the present specification.

To the extent that this assumption might have a bearing on the propriety of an obviousness-type double patenting rejection, it is respectfully submitted that the assumption is incorrect. As discussed above in connection with the § 112, second paragraph rejections, the specification provides a detailed definition of what it means for one plant to be a "derivative" of another. That discussion will not be repeated here in the interest of brevity, but it is respectfully submitted that the response to the § 112, second paragraph rejection pertaining to "derivatives" also answers the Office's contention here. In brief, Claim 1 requires that the rice plant must, among other things,

have herbicide resistance characteristics that may be traced back to the deposited line PTA-904.

Furthermore, element (c) of independent Claim 1 specifically requires that "said plant has the herbicide resistance characteristics of the plant with ATCC accession number PTA-904." Thus the nature of the herbicide resistance characteristics of the derivative Claims is clearly taught by the specification.

(c) Under the correct legal standard, applied correctly to the facts of this case, there is no obviousness-type double patenting, provisional or otherwise. As previously discussed, the correct legal standard is whether any claim in the present application defines an invention that is merely an obvious variation of an invention claimed in the cited application. Furthermore, in considering whether the invention defined in a claim of the present application is an obvious variation of the invention defined in a claim of the cited application, the disclosure of the latter may not be used as prior art. Any obviousness-type double patenting rejection (whether provisional or otherwise) should make clear: both the differences between the inventions defined by the conflicting claims; and the reasons why a person of ordinary skill in the art would conclude that the invention defined in the claim at issue is an obvious variation of the invention defined in a claim in the cited application.

The Office Action did not even attempt to apply this standard to the provisional double-patenting question. To support this ground of rejection, at a minimum the Office should identify at least one specific Claim from the '973 application, and at least one specific Claim from the present application, and then explain why a person of ordinary skill in the art would conclude that the latter would have been obvious in light of the former. It is respectfully submitted, however, that this is not the case.

For example, Claim 62 of the '973 application currently reads as follows:

62. (once amended) A herbicide-resistant rice plant, wherein:

- (a) the growth of said herbicide-resistant plant is resistant to inhibition by at least one herbicide that normally inhibits acetohydroxyacid synthase, at levels of the herbicide that would normally inhibit the growth of a rice plant; and
- (b) said herbicide-resistant plant is a derivative of a rice plant obtained by exposing rice plants to mutation-inducing conditions; growing rice plants from the exposed plants, or growing rice plants from progeny of the exposed plants, in the presence of at least one herbicide that normally inhibits acetohydroxyacid synthase, at levels of the herbicide that would normally inhibit the growth of a rice plant; and selecting for further propagation rice plants that grow without significant injury in the presence of the herbicide; and
- (c) said herbicide-resistant plant expresses a functional acetohydroxyacid synthase that is resistant to inhibition by at least one herbicide that normally inhibits acetohydroxyacid synthase, at levels of the herbicide that would normally inhibit the growth of a rice plant;

provided that excluded from the scope of this Claim is:

- (d) a plant that is the plant with ATCC accession number 97523; and any mutant, recombinant, or genetically engineered derivative of the plant with ATCC accession number 97523 or of any progeny of the plant with ATCC accession number 97523; and any plant that is the progeny of any of these plants; wherein these derivatives of the plant with ATCC accession number 97523 that are excluded from the scope of this Claim are those that have the same herbicide resistance characteristics as the plant with ATCC accession number 97523.

By contrast, Claim 1 of the present application reads as follows:

1. (currently amended) A rice plant wherein:

- (a) the growth of said plant is resistant to inhibition by one or more of the following herbicides, at levels of herbicide that would normally inhibit the growth of a rice plant: imazethapyr, imazapic, imazapyr, nicosulfuron, imazaquin, imazamox, metsulfuron methyl, thifensulfuron methyl, tribenuron methyl, pyrithiobac sodium, or a derivative of any of these herbicides; and
- (b) said plant is a derivative of the plant with ATCC accession number PTA-904; and
- (c) said plant has the herbicide resistance characteristics of the plant with ATCC accession number PTA-904.

The Office has the initial burden of establishing a *prima facie* case of obviousness, just as in any other obviousness rejection; with the exception that obviousness is judged in view of an individual claim of the '973 application -- the remaining teachings of the '973 specification may not be treated as prior art. The Office has not met this initial burden.

Because the Office has not met its initial burden of establishing a *prima facie* case of obviousness over any claim of the '973 application, Applicant has no obligation to rebut the assertion of obviousness. However, in the hope of possibly accelerating prosecution, some comments are offered below why the claimed inventions would not have been obvious over the '973 Claims, taking independent Claim 62 from the '973 application and Claim 1 from the present application as examples.

These two Claims stand in the relation of genus and species.

A teaching of a genus does not necessarily render individual species obvious. See, e.g., the extended discussion in M.P.E.P. § 2144.08 on this topic. The mere fact that M.P.E.P. § 2144.08 is so lengthy shows that one cannot draw a simple conclusion that a generic teaching necessarily makes a species within the genus obvious. Were

there indeed such a simple, black-and-white rule, then M.P.E.P. § 2144.08 could have been written in no more than a paragraph or two.

In particular, there is nothing in Claim 62 of the '973 application that suggests any particular variety or line of herbicide-resistant rice, other than the ATCC 97523 line mentioned in the "negative" limitation of element (d) of that Claim. Keeping in mind that only the Claim may be considered, and not the specification of the '973 application, a Claim directed generically to herbicide-resistant rice having certain characteristics does not make obvious any particular "species," i.e., variety or line, within that genus. If the teachings of the '973 specification were available as prior art, then this conclusion might be different; but in the absence of those teachings, which is how double patenting issues must be assessed, it is difficult to see how any particular variety or line within the scope of the generic claim might be specified with any reasonable expectation of success.

To help illustrate this point, the following "thought experiment" may be helpful: Without reference to anything in the '973 specification other than a selected, single Claim from that application, such as Claim 62 -- attempt to provide an enabling description of a specific variety or line falling within the selected Claim: What are the specific characteristics of the variety or line? How does one make and use the specific variety? What are its specific herbicide resistance characteristics? Probably the only variety or line for which it might be possible to do this would be ATCC 97523, which is the one variety that is specifically mentioned in Claim 62. But ATCC 97523 and its derivatives fall outside Claim 62; indeed, ATCC 97523 is described in Claim 62 only as part of a negative limitation, to specify that ATCC 97523 and its derivatives are outside the scope of the Claim. It is respectfully submitted that it is not possible to give an enabling description of any particular rice variety or line that would fall within the scope of generic Claim 62 of the '973 application, with any reasonable expectation of success, based solely on Claim 62 of the '973 application, and without reference to anything else in the '973 specification.

It is therefore respectfully submitted that no obviousness-type double patenting rejection of any claim in the present application may properly be based on any claim of the '973 application.

Note that nothing in the foregoing argument depends on the particular characteristics of PTA-904. Nevertheless, in the hope of possibly accelerating prosecution, Applicant will also show that PTA-904 has surprising, nonobvious properties. Even if one did not accept the argument just given; and even if one assumed for the sake of argument that, without reference to the '973 specification, Claim 62 of the '973 application alone might, with a reasonable expectation of success, allow one to give an enabling description of one or more particular rice varieties or lines that fell within the scope of generic Claim 62 of the '973 application -- even with all these assumptions, it would nevertheless be the case that PTA-904 has surprising, nonobvious properties that could not have been predicted with any reasonable expectation of success. A double patenting rejection of the present Claims would therefore still be improper.

Nothing in Claim 62 of the '973 application suggests the surprising, and markedly superior herbicide resistance characteristics expressed by PTA-904. Please see the enclosed new Affidavit of inventor Timothy P. Croughan, which demonstrates that PTA-904 has herbicide resistance characteristics that are substantially different both from the herbicide response characteristics of a "wild type" non-resistant variety, and from the herbicide resistance characteristics of ATCC 97523, the resistant line that is mentioned in the negative limitation of Claim 62 of the '973 application.

(Applicant notes for the record that a terminal disclaimer was preemptively filed in the '973 application over the present application, in order to circumvent possible double patenting issues in the '973 application. In other words, Applicant has voluntarily elected not to contest a hypothetical obviousness-type double patenting rejection of the generic claim over the specific claim, although Applicant does contest the provisional rejection of the specific claim over the generic claim.)

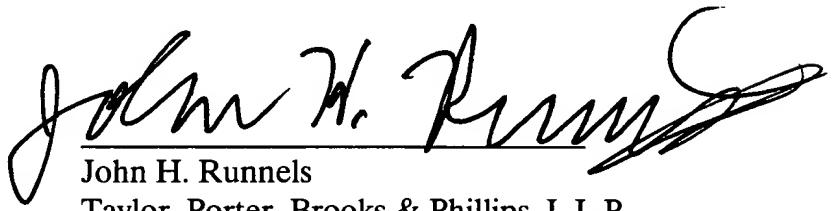
It is respectfully submitted that the provisional obviousness-type double patenting rejection should be withdrawn.

Conclusion

The Office is respectfully requested to re-mail an initialed copy of the July 30, 2001 Information Disclosure Citation, marked to show that all references cited on page 4 were considered, not just the first and last entries shown on that page.

Allowance of Claims 1-5, 7-9, 11, 13-15, 31, 38, 54, 61, 129-132, 134-136, 138, 140-146, 148-150, 152, 154-160, 162-164, 166, and 168-185 at an early date is respectfully requested.

Respectfully submitted,



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May 13, 2003

Appendix C

Copies of
ATCC Budapest Treaty Forms

10801 University Blvd • Manassas, VA 20110-2209 • Telephone: 703-365-2700 • FAX: 703-

BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF
THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

INTERNATIONAL FORM

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT ISSUED PURSUANT TO RULE 7.3
AND VIABILITY STATEMENT ISSUED PURSUANT TO RULE 10.2

To: (Name and Address of Depositor or Attorney)

Taylor, Porter, Brooks & Phillips, L.L.P
Attn: John H. Runnels
P.O. Box 2471
Baton Rouge, LA 70821-2471

Deposited on Behalf of: Board of Supervisors of Louisiana State University and Agricultural and Mechanical College (Ref. Docket 98A9-PCT)

Identification Reference by Depositor: Patent Deposit Designation

<i>Oryza sativa</i> L. rice seeds:	CMC29	PTA-902
	CMC31	PTA-903
	PWC 16	PTA-904
	PWC23	PTA-905

The seeds were accompanied by: a scientific description a proposed taxonomic description indicated above.
The seeds were received November 2, 1999 by this International Depository Authority and have been accepted.

AT YOUR REQUEST: We will inform you of requests for the seeds for 30 years.

The seeds will be made available if a patent office signatory to the Budapest Treaty certifies one's right to receive, or if a U.S. Patent is issued citing the seeds and ATCC is instructed by the United States Patent & Trademark Office or the depositor to release said seeds.

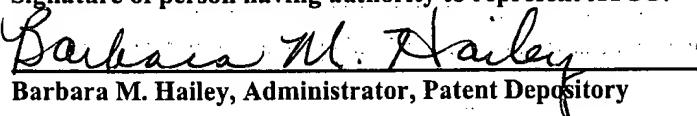
If the seeds should die or be destroyed during the effective term of the deposit, it shall be your responsibility to replace them with viable seeds of the same.

The seeds will be maintained for a period of at least 30 years from date of deposit, or five years after the most recent request for a sample, whichever is longer. The United States and many other countries are signatory to the Budapest Treaty.

The viability of the seeds cited above was tested November 22, 1999. On that date, the seeds were viable.

International Depository Authority: American Type Culture Collection, Manassas, VA 20110-2209 USA.

Signature of person having authority to represent ATCC:


Barbara M. Hailey, Administrator, Patent Depository

Date: November 22, 1999

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Baton Rouge, LA 70821-2471

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Mechanical College (Ref. Docket 98A9-PCT)**

Identification Reference by Depositor: **Patent Deposit Designation**

<i>Oryza sativa</i> L. rice seeds:	WDC33	PTA-906
	WDC37	PTA-907
	WDC38	PTA-908

The seeds were accompanied by: a scientific description X a proposed taxonomic description indicated above.
The seeds were received November 2, 1999 by this International Depository Authority and have been accepted.

AT YOUR REQUEST: X We will inform you of requests for the seeds for 30 years.

The seeds will be made available if a patent office signatory to the Budapest Treaty certifies one's right to receive, or if a U.S. Patent is issued citing the seeds and ATCC is instructed by the United States Patent & Trademark Office or the depositor to release said seeds.

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Barbara M. Hailey
Barbara M. Hailey, Administrator, Patent Depository

Date: November 22, 1999